

# THE POINT

A newsletter for and about the people of the  
U.S. Army Medical Research and Materiel Command

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## Alaska shelter chosen as interim tent solution

Church choirs, Bob Dylan and the Rolling Stones have all sung of the need for shelter. And in December 2002, the Army Medical Department began singing the praises of a new shelter for its combat support hospitals.

A mandate from the Army to see what shelters would best suit the Army medicine's needs precipitated a review of new shelter types, said Mike Beaulieu, project manager, Army Commercial Medical Systems for the U.S. Army Medical Materiel Agency.

"We were due to buy more replacement TEMPER (tent expandable modular personnel, the current shelter used in the Deployable Medical System), but the Surgeon General said, 'Before we do that, let's take a look at what's out there so what we buy in the interim—between what the service has and where it's going—is what we really need,'" he said.

While the Navy, Air Force and Marine Corps, in varying degrees, have moved to other tent platforms for all or part of their medical capabilities, the Army was the lone hold out in continuing to use TEMPER.

To pick the best tent to take the Army combat support hospital toward transformation, the Army Medical Department Center and School convened a "tent off" last year at Camp Bullis in San Antonio to see what industry had to offer. Army users evaluated four shelters: a modified TEMPER, the Alaska Shelter (which the Air Force uses for its medical shelter), BASE X (which the Marines use for a medical shelter) and GMA Cover Corp.

During the December tent off, evaluators examined the shelters' engineering, ease of set up and compatibility with the DEPMEDS and equipment. The board then compiled responses addressing the pros and cons of each

shelter and delivered them to Terry Lee, test coordinator for the U.S. Army Medical Research and Materiel Command.

The results? "Though there were benefits and shortfalls for each, the results were that the Alaska shelter appeared to be favored for the combat support hospital," said Steve Reichard, product manager from the U.S. Army Medical Materiel Development Activity.

The Alaska shelter was quicker and more straightforward to set up, said Lt. Col. Phillip Langworthy, a combat developer from the Army Medical Department Center and School.

"There are multiple tents in a combat support hospital, so the time needed to pitch the tents grows exponentially depending if it's an 84-, 164- or 248-bed combat support hospital," he said. Quicker is better, especially when there are 22 64-foot sections in a full combat support hospital and five 16-foot sections and 11 64-foot sections needed to create an 84-bed hospital.

The Alaska shelter's domed, Quonset hut design also weathers elements better, Langworthy said. "The environmental load parameters of rain, wind and snow are generally accepted as better in Quonset-shaped tents because they don't present the flat surfaces like a (boxy) TEMPER that can catch wind and (collect rain and) snow," he said.

An additional characteristic of the Alaska shelter that impressed the AMEDD soldiers was its interior, which provides more space to work in and has a brighter interior so soldiers can see better.

However for all its strengths, the Alaska shelter needed a few modifications, Lee said.

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## Container lets medics take blood far forward

The new Golden Hour blood container that lets medics take blood far forward in battle brings to fruition the vision of a three-person staff at the Blood Research Department at Walter Reed Army Institute of Research.

"A number of surgeons who were there came back (from Afghanistan in April 2002) and said they were concerned about getting blood far forward ... (because there are) small groups going out (and face) delayed evacuation time," said Col. Tom Reid, chief of the Department of Blood Research at WRAIR.

In fact, Reid said, during Operation Anaconda, an Air Force Special Operations medic who packed units of blood saved the life of a badly

wounded Ranger in Afghanistan.

During the April discussions, the recurring question the surgeons asked was "Do we actually need blood far forward and, if so, what are we doing about it now?" Reid said.

Transporting blood, which is regulated by the Food and Drug Administration, is no simple task. "You can't just throw it in your ruck (like you can with IV solutions)," said Col. John Holcomb, a trauma surgeon and the Army surgeon general's trauma consultant.

In the past, medics put units of red blood cells in coolers filled with wet ice to keep blood at its optimal temperature of between 1 and 10 de-

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### 'Shelter' from page 1



*Soldiers try their hand at putting up the modified Alaska shelter at Fort Indiantown Gap, Pa., in July. The shelter was chosen as the Army's interim shelter solution for combat support hospitals.*

"The AMEDD Center and School ... want to use everything associated with TEMPER in Alaska (so it plugs into the DEPMEDS)," he said. "You save a lot of money that way because you don't have to purchase new equipment."

To ensure a good fit, the Army asked the shelter's manufacturer

to add windows and side doors, widen the entrance from four to five feet, fit it with chemical-biological protective liners, move an air handling duct and modify a pole so the current TEMPER power box would fit on it.

The company shipped two prototypes to Fort Indiantown Gap, Pa., for an assessment in July. During the assessment, developers asked for additional modifications, such as moving the air conditioning plenum so it didn't block a passageway and lowering where the equipment was mounted on a power pole so it's easily reached.

Though the Alaska offers no substantial improvement when it comes to reducing shelter weight and packed size, an emerging technology may one day lighten the load. Air beam framing systems that use air-filled arched tubes of woven composite materials as ceiling and wall supports fit within the Alaska shelter's design.

"They're very strong," said Reichard, who has a photo of a car suspended from the top of an air beam. "You can 'plink' the beam with your finger and see they're very solid. It also hurts your finger."

Right now, air beam technology isn't mature enough to be included in the interim solution, but Reichard said he thinks it will be ready in the next five to 10 years. It will, he said, be part of the Future Medical Shelter System.

Air beams, which could cut the shelter's weight by almost two thirds, also go up very quickly with a portable air compressor.

"You can get a tent up, from unloading it from a vehicle to putting it up, in 10 to 15 minutes," Reichard said.

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grees Celsius. "When your (outside) temperature is 110 (degrees Fahrenheit) or is cold, the units of red blood cells won't stay at the right temperature for very long," said Dr. Victor Macdonald of WRAIR.

When blood isn't kept at the right temperature, cell membranes break down in a process called hemolysis, which can cause kidney failure and death if bad blood is given to patients.

After creating five or six prototypes, a Minnesota company arrived at the Golden Hour container. Its name is based on the tenet that beating the effects of shock within the first hour of injury—by giving a blood transfusion, for instance—is vital to trauma patients' survival.

"We bleed out the oxygen-carrying capability on to the ground and at some point you get sick enough that you need to replace that," said Holcomb, who also is the commander of the U.S. Army Institute of Surgical Research in San Antonio.

The container, a nearly 10-inch square box that needs no power source to maintain its internal temperature, uses a combination of the vacuum-insulated panels and an internal container that has a liquid phase-change material, like the reusable freezer packs people toss in coolers.

"The black, internal portion of the container is put in a refrigerator or freezer for at least two hours, then is put back in the container along with the units of red blood cells. The lid is put on, and that's it," Reid said.

The container, which has a strap for carrying and comes in Army desert and woodland camouflage and Marine camouflage, can hold four units of red blood cells and weighs 10 pounds when it's full.

"The point of the box is for the medic to have blood with him, ready to use when he needs it," Reid said. "We hope to have it lighter in future iterations."

How long the blood stays usable in the container depends on the outside temperature, said Lt. Col. Frank Rentas, assistant chief of blood research at WRAIR. According to tests run in the Blood Research Department, when the outside temperature is -9 degrees Fahrenheit, the red blood cells stay good for more than 97 hours; at 105 degrees Fahrenheit, they're good for more than 78 hours; and at room temperature, they can last 121 hours.

"The beauty of this is that the box isn't just good for red cells but for anything that needs to be transported forward like biologicals, vaccines, reagents," Rentas said.

The WRAIR team is already looking at a second-generation box that can constantly monitor the internal temperature of the box. Right now, the advice the researchers have given the Special Forces customers who purchased 20 boxes is to use temperature-sensitive stickers that indicate when blood's gone below or above the recommended temperature.

The solution to red cell replacement on the battlefield, Reid said, may be a hemoglobin-based oxygen carrier. Also called HBOC, the solution could do the red blood cells' oxygen-carrying job and be thrown in a medic's rucksack. The product is currently working its way through the FDA approval process. This approach, combined with new hemostatic dressings, may significantly decrease mortality on the battlefield, Holcomb said.



*Lt. Col. Frank Rentas checks the temperature of blood being cooled by the Golden Hour container.*

## Command plans new research info system

A six-year-old Food and Drug Administration regulation pertaining to electronic records and signatures will change the way the Army's medical researcher does business in the coming years.

The team developing MeRITS, which stands for Medical Research Information Technology System, is steadily gaining ground on just what changes—to software, hardware, training, personnel and procedures—will need to take place in U.S. Army Medical Research and Materiel Command labs to ensure the FDA will continue to accept research data coming out of the labs.

"If our mission is to develop medical products to protect our deployed military personnel, the warfighters, then we have to comply with FDA regulations (on the use of computers in regulated research)," said Col. Ralf Brueckner, who's leading the MeRITS project.

The regulations originated when industry asked the FDA for permission to submit research documentation electronically instead of shipping boxes upon boxes of paper research data. The FDA agreed to the request with several important conditions, including, for example, that the submitter had to ensure electronic documents had an audit trail as trustworthy as a paper one.

To submit electrons, then, the command needs to provide "assurance to the FDA that what they're receiving is trustworthy and reliable, that from the beginning to the end you can point to who had access to the information, who has changed it and where the electrons have been," said David Dasso, the second member of the two-person MeRITS team.

Further, the command's labs have to ensure "the data we spend so many millions of dollars developing and investing in is collected and stored and can be retrieved and transmitted and there are back up and disaster recovery plans in place," Brueckner said.

Though it sounds easy enough, it isn't. In fact, Brueckner said surveys indicate some of the larger companies are spending \$100 to \$200 million to address the problem of how to comply with the regulation.

"The implications of the regulation took a while to sink in," Brueckner said. "I think that's true not just for our organization but across the entire biopharmaceutical industry."

Not complying with FDA regulations on electronic records and signatures can have dire consequences.

"They (the FDA) could disqualify data, disqualify investigators and not approve a product," said Dasso. "Tens if not hundreds of millions of dollars go into the work leading up to FDA submissions and (you wouldn't want) to have the FDA say it can't make an 'approve' decision because they have concerns about the integrity of the data."

What makes adhering to the guidelines a challenge is the electronic audit trail. "You don't necessarily know who the author of a document is or who had access to it," Dasso said. "In the past, because the data trail was a paper one, researchers lined through changes to make them obvious to an FDA reviewer, but with electrons, changes can be made at any time ... and there's no way to know what the original document looked like without having a paper copy, "

For months, Brueckner, Dasso and consultants have been assessing busi-

"Tens if not hundreds of millions of dollars go into the work leading up to FDA submissions and (you wouldn't want) to have the FDA say it can't make an 'approve' decision because they have concerns about the integrity of the data."

—David Dasso,  
Medical Research  
Information  
Technology System  
team member



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**MeRITS' from page 4**

ness processes at the command's labs and activities, including the Walter Reed Army Institute of Research and its two overseas labs in Thailand and Kenya, the U.S. Army Medical Research Institute of Infectious Diseases, the command's RCQ directorate, U.S. Army Medical Materiel Development Activity and the U.S. Army Medical Information Systems and Services Agency. The visits will help shape the command's system.

"We haven't visited all the labs yet, but what we have done is visited enough of the labs so we know there are common problems that can benefit from common shared solutions," Brueckner said.

The solution isn't just buying a computer and software, he said. "We are looking at some of the business processes and the people, including people (like quality assurance and help desk personnel) who we don't have but need to be in place for this system to realize its full potential," the colonel said. With researchers' assistance, the MeRITS team will also develop command-wide procedures for labs to follow to ensure their data meet the FDA's regulations.

During the assessment phase, which is nearly complete, the MeRITS team is also looking at the many computer systems labs currently use to see what capabilities they offer and which comply with the regulations.

"Various departments and investigators, over the years, have developed their own unique ways of trying to address the requirements and their needs, and there are various degrees of sophistication depending on how well they understand computers, the regulations and what resources are available," Brueckner said.

"What we're really trying to do is move the command away from an investigator-driven (method) in which each investigator has his or her own computer system to a corporate-driven approach, so it's the Army's data, the command's documents," he said.

Before making a final selection, the MeRITS team plans to talk to drug and vaccine compa-

nies to see what systems have worked best for them.

"Once we have our requirements set, we can talk to them about what worked well for them and what didn't," the colonel said. "We anticipate that when we get to the consulting stage, we'll hear that those companies are struggling with the same issues."

Both Brueckner and Dasso see real benefits coming from the command having a central repository for research data and documents, especially protocols, reports, case report forms, informed consent forms and templates.

"When a researcher sets out to write a report or an informed consent form, the command will have predefined what elements need to be in the document so the researcher will just fill in the template," Brueckner said. "Forms and protocols won't be kicked back because they were incomplete or didn't meet the command's standards."

Having the data available in real time will also let researchers quickly spot trends, like adverse events or lab values, and answer queries on the study's progress, like the number of subjects that are enrolled or how many have received a dose of vaccine or a drug. Real time data will also enable the researcher to write a report at the moment the last subject is released instead of taking weeks to cull the information and enter it into a system.

Researchers will be better able to access other researchers' work because it will be stored in an electronic archive. Bruckner said he hopes preclinical data and lab notebooks will one day find their way to the archive as well.

Right now, it's too soon to say just what the final system will look like or when it will be fully in place. Brueckner and Dasso agreed the system will be a commercial product or service, phased in over time so it won't present an abrupt change to business practices. Spring 2004 should bring the first changes with the initial pieces of the document archive system. A data management system should start inching in a year later.

## Cadets see health facility planning up close

College engineering majors took their future degrees on road trips this summer to help plan the Army's future healthcare facilities.

After completing their leadership training at Fort Lewis, Wash., five



*Health Facility Planning Agency ROTC interns Cadets Elizabeth Papapietro and Peter Gustafson meet with Capt. Dan Leary, company commander at the U.S. Army Medical Research Institute of Infectious Diseases.*

Army Reserve Officers' Training Corps cadets spent three weeks of their summers as interns with the Health Facility Planning Agency offices. The agency is a small, subordinate command of the Medical Research and Materiel Command, with a unique mission to support the Army Medical Departments

\$9 billion of facilities located around the world.

"Our hope is to be able to market the MSC (Medical Service Corps) to ROTC cadets to find talent in engineering and architecture who might be interested in working for us in managing the planning, design and construction of Army medical Department medical treatment and research facility projects," said Col. Rick Bond, the agency's commander. "If we're successful in getting five cadets a year, which is pretty unusual ... and we're able to recruit two, that's pretty good. That's two more than we knew about."

Cadets applied for the agency's internship program and had a choice of working in the Falls Church, Va.,

headquarters or four project offices around the globe in Korea, Alaska, Hawaii or Washington, D.C.

During Cadet Elizabeth Papapietro's three-week stint in Virginia, she was not only exposed to Surgeon General staff-level operations, but also to ongoing construction projects as diverse as the renovation of lab facilities for the Center for Environmental Health Research on Fort Detrick and the health and dental clinic at the Alternate Joint Communications Center.

"Basically, I wanted the experience of seeing how the Army works. I'm not going to be in a combat arms branch when I'm finally commissioned, so I wanted experience outside the ROTC world," the Lehigh University cadet said.

That's what the program is about, said Paul Kotakis, chief of the Public Affairs Division for U.S. Army Cadet Command.

"This presents an opportunity for the cadets to gain additional information and gain insight into one dimension of the Army, and then they're in a good position to decide if it's a good match for them," he said.

In fact, Col. Rick Bond's experience 25 years ago led him to his current job as the Health Facility Planning Agency's commander. An architecture student, he spent his three-weeks internship with the Army Corps of Engineers at Fort Gordon, Ga., grading parking lots, digging rifle range firing points, building dog kennels and running bulldozers.

After that experience, he said, "There's no way in the world I can spend four years doing this."

Concerned about his future Army career, he headed home to Massachu-

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## Laser to play role in lab's combat readiness test

The U.S. Army Research Institute of Environmental Medicine is testing an innovative biosensor designed to measure combat readiness of soldiers in training. The biosensor is intended to provide field measurements of Insulin-like Growth Factor-1 in a soldier's interstitial fluid and to monitor changes during physical combat training exercises.

IGF-1 is a metabolic hormone that, among other things, regulates the growth and repair of muscle tissue. The goal of monitoring IGF-1 is for soldiers to maintain peak combat readiness and reduce physical stress and injury. Low levels of IGF-1 may indicate that a soldier's body may be overly stressed.

ISF is the clear fluid in the body through which nutrients pass from the blood stream to the cells. Scientists believe that using ISF could be more beneficial than using blood because it

is closer to where the IGF-1 is used by the body's cells.

A small, hand-held laser reaches the ISF by creating microscopic holes, or micropores, in the outer layer of dead skin. This technology allows for the ISF to be tested with a small sensor patch worn over the micropores. No blood is drawn.

The research initiative is part of the Army's Technologies in Metabolic Monitoring Research Program. Dr. Bradley C. Nindl, the principal investigator at USARIEM, will develop and manage these studies.

The U.S. Army is currently undertaking several studies aimed at ensuring peak physical performance for soldiers during periods of military operational stress. Nindl believes that measuring IGF-1 in ISF during physical stress studies will provide new insights into understanding human performance.

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setts. One stop he made along the way turned him around. After spending a day with the agency's health facility planners in the Pentagon, Bond knew he'd found his calling.

At day's end, when the planners asked when Bond could start, he replied "How soon can you make sure I end up here?" When he returned to school, he asked to join the Medical Service Corps as a health facility planner, a subset of the medical logistics career field. His first duty station as a "butter bar" in 1979 was in the Pentagon office he visited the summer before graduating.

Getting engineering and architecture majors' attention early is one reason the Health Facility Planning Agency offers the internships, said Eric Yoshihashi, the agency's administrative officer who coordinated the cadets' visits.

"We, in the past, noticed Engineer Corps officers were asking to branch transfer to the Medical Service Corps to be part of HFPA," he said. "The reason they didn't come into our corps first was they didn't know the agency existed."

Yoshihashi said the agency hopes the cadets

leave with an understanding of how the agency performs lifecycle management and manage projects for medical, dental, veterinary and medical research facilities.

"We want to show them that, when we start working on projects, we take into consideration how we can best serve them—both patient and patient providers—so the best possible health care facility is provided for them and their families," he said.

For Cadet Scott Poznanski from Washington University in St. Louis who spent his weeks at Fort Wainwright, Alaska, where the HFPA office is involved in managing the construction of a \$215 million replacement hospital facility, the experience solidified his career choice.

"I feel I have had a very in-depth look at what I want to branch, and it only makes me more excited," he wrote in his after-action questionnaire.

Having the interns around also reenergized the more seasoned planners, Bond said. "They (the interns) are open to everything. They think it's all cool, and they remind us that we ourselves sometimes forget how cool our mission really is," he said.

## Europe unit gets medical supplies to theater, soldiers

**"We have more supplies than our warehouses can hold. We have had to come up with creative ways to store our products."**

**—Col. Jettaka Signaigo, commander, U.S. Army Medical Materiel Center Europe**

A hospital without medical materiel support is like a rifle without bullets. Even the world's greatest marksman cannot do his job effectively without ammunition, and a hospital is only as good as its supplier.

The U.S. Army Medical Materiel Center, Europe, located near Pirmasens, Germany, is the primary supplier of medical materiel for military operations in Europe, Africa and Southwest Asia. USAMMCE also supports many nonmilitary operations such as embassies.

Every medical supply item in the European theater—from eyeglasses to combat hospital equipment—has at one time passed through the hands of the USAMMCE staff, according to Col. Jettaka Signaigo, USAMMCE's commander.

During the recent war in Iraq, USAMMCE's role became even more vital. And, with their expanded mission, new challenges presented themselves nearly every day. Signaigo said one of the major challenges they faced was the lack of storage space for the additional supplies that had to be received, stored and shipped.

"We have more supplies than our warehouses can hold. We have had to come up with creative ways to store our products. We've identified every inch of space available on this installation," she said.

Some of the creative methods include storing items in the open shed where vehicles arriving at the gate are inspected and using tractor-trailer refrigerators. Nearly every place under cover has been used as storage.

"Our inventory is only limited by one's imagination," Signaigo said, adding that it is difficult to maintain



In the busy warehouse of U.S. Army Medical Materiel Command, Europe, employees work long hours to ensure medical supplies reached those caring for troops participating in Operations Iraqi Freedom and Enduring Freedom.

adequate inventory of every item that could possibly be requested, considering USAMMCE is required to supply whatever a military medical facility deems necessary for its mission.

USAMMCE regularly stocks more than 7,000 line items, and more than 40,000 additional lines are cataloged and can be ordered by customers. But, medical facilities can order any conceivable medical supply, and USAMMCE will get the item and add it to the catalog if the item is deemed necessary by command surgeons.

For Operations Iraqi Freedom and Enduring Freedom, military medical facilities ordered more than \$98 million in medical supplies and equipment as of mid-May.

Sometimes the delivery of a particular item is a matter of life and death. Signaigo recalled one instance during Operation Iraqi Freedom when 16 patients on a Navy hospital ship were in desperate need of a special type of antibiotic due to an infectious outbreak.

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USAMMCE' from page 8

When USAMMCE's Navy liaison received the request, the USAMMCE team went to work fast. The antibiotic was pulled from the warehouse, rushed to the airport and then flown to the Middle East. It went by helicopter to the physician on the ship. The total time from the moment the request was received to the moment the product was in the hands of the healthcare provider was 26 hours. It reached the patients in time to save their lives.

Working such logistical miracles takes many people, both inside and outside the command.

"Without the assistance of the 418th Medical Logistics Company, deployed to USAMMCE since early December from Fort Sam Houston, [Texas], soldiers from the 226th Medical Logistics Battalion in Miesau, Germany, and three Air Force Expeditionary Medical Logistics Teams, USAMMCE would not have had the manpower needed to accomplish the increased workload created by OEF and OIF," Signaigo

said.

Its U.S. and local national civilians worked overtime, too. About two-thirds of the staff is German.

"When we brought up the possibility of mandatory overtime for our local national employees, many came forward to volunteer to work extra hours," according to Johannes Bereswill, deputy for integrated processes and quality management and himself a 21-year local national employee. "The willingness of military and civilian personnel to work long hours and weekends really made the difference."

Despite the challenges the organization encounters, Signaigo said the organization's personnel attempt to make the process as seamless as possible for the customer.

"We don't want the customer to know how complicated the process is," she said. "All we want them to know is that within days of placing an order, the products get delivered."

—Europe Regional Medical Command

## USAMMCE feeds multitudes at fest

Americans and food are irrevocably linked for Sister Antonella. When she was a child in 1945, American soldiers moved into her family's house supplying enough food to feed her starving family. Those soldiers gave Sister Antonella her first taste of chocolate, a memory that lights her face even now.

Recently, Americans again came to Sister Antonella's aid, bearing gifts of food and more. Soldiers and civilians of the U.S. Army Medical Materiel Center, Europe gave up part of their Fourth of July weekend to volunteer their help at the Nardini Haus Friendship Fest.

The 148-year-old Nardini Haus is a group of orphanages operating locally in the Pirmasens and Zweibruecken communities. Sister Antonella belongs to the order of nuns established at the same time the orphanage was founded and runs one

of the two Nardini Haus orphanages in Pirmasens.

On July 5, the Nardini Haus conducted its seventh annual "Nardini Freundschaftsfest," and Team USAMMCE provided enough burgers, hot dogs and bratwurst to feed the approximately five hundred attendees. Funds to provide the food were raised at USAMMCE bake sales.

"This is the first time Americans have participated in the Fest, but it won't be the last," said Col. Jettaka Signaigo, USAMMCE commander, who pledged USAMMCE's further assistance to the orphanage.

"The hamburgers were good, and I'm glad that they made them. And, the people were really friendly, too," said Nadine Thesen, an orphanage resident. Her friend, Jessica

See 'Fest', page 10

## Defense dollars fight rare leukemia

As the Congressionally Directed Medical Research Programs' newest program, the Chronic Myelogenous Leukemia Research Program's aim is clear: to eradicate CML.

Caused by an overgrowth of a type of white blood cell called a granulocyte, CML accounts for about 20 percent of adult leukemias in Western countries. With symptoms of lethargy, night sweats, bruising, bleeding gums, anemia and white blood cell counts of 50,000 (normal range runs between 4,500 to 5,000), in 2002 CML was the diagnosis for about

4,400 people and the reason 2,000 died.

At the research program's beginnings, officials at the CDMRP brought together clinicians, researchers and CML survivors in April 2002 to decide where research money needed to be spent. In addition to understanding the basic science behind the disease, the stakeholders, as the group was called, also decided to seek additional drugs to fight it.

One drug, Gleevec, available since May 2001, has given hope to many CML patients, but three percent of

See 'Leukemia', page 11

Fest from page 9

Trautmann, wanted to know how the hamburgers were made because

"they were so good."

A number of USAMMCE personnel manned the food booth and grills while others established a soft ball field (of sorts) with bases, softballs, bats,

and a t-ball stand they had brought along. Several USAMMCE soldiers tossed an American football back and forth with the kids, while still others played half-court basketball.

"The baseball was great," said Mattias Zimmerman, a resident teenager who was more interested in the baseball than the food. "They taught us how to play. Oh yeah, the ham-

burgers were good, too."

Frau Renate Gerlich, managing director for the Nardini Haus Group, explained that the Nadine Haus currently ministers to 300 children ranging in ages from three weeks to age twenty-two. The group has a daycare facility, Kindergarten, and a school that encompasses Elementary to High School.

One hundred and ten children live on the premises, with some going home to foster families on the weekends. A number of the children are handicapped, not so much physically as mentally and emotionally. Additionally, many of the families and the children are extremely poor.

The Nardini Freundschaftsfest is a way to integrate the children of the orphanage with the people of the community. Providing food and games at little or no cost is a way to encourage the families to attend, and volunteering organizations, such as USAMMCE, make the Fest possible.

Sister Antonella can look forward to next year when Americans will again arrive bearing gifts of food.

—Cheryl Navo, USAMMCE



At the "Nardini Freundschaftsfest," USAMMCE soldiers and children played t-ball, tossed an American football back and forth and played half-court basketball.

**'Leukemia' from page 10**

patients taking it develop resistance in 18 months, said Dr. Alan Kinniburgh, vice president of research administration at The Leukemia & Lymphoma Society and a participant in the stakeholders meeting.

"The consensus was we should look toward research that can find ways of countering the resistance, by creating a new drug so when Gleevec doesn't work, it steps in and does the job of battling the leukemia. It's the rare cancer that can be defeated with a single drug or single agent," he said.

Once goals were set, the announcement asking for proposals went on the Web in June. By the mid-September cutoff date, four dozen proposals had arrived. A second group—which also included CML patients, researchers and clinicians—convened to scientifically peer review the 48 proposals.

David Cranmer, active in a local chapter of the Leukemia and Lymphoma Society, was one of three survivors invited to join the review process. Once he was assured that his experience and the ability to speak for other CML patients were the only prerequisites, Cranmer agreed to help. "Basically we (the CML survivors) had to look at if what was being proposed was something we, as patients, would be willing to do," he said.

Having patients review proposals is a hallmark of the CDMRP process, said Col. Melissa Forsythe, deputy director of the Congressionally Directed Medical Research Program and CML Research Program manager. Including survivors lets scientists "put a face to the disease so they can see the urgency to their work," she said.

What also sets this program apart is CDMRP's willingness "to go out on a limb and fund research that no one else would fund," said Dr. Julie Wilberding, grants officer representative for the CML program.

"CDMRP is very cutting edge," said Kinniburgh, who was a professor of cancer genetics at Roswell Park Can-

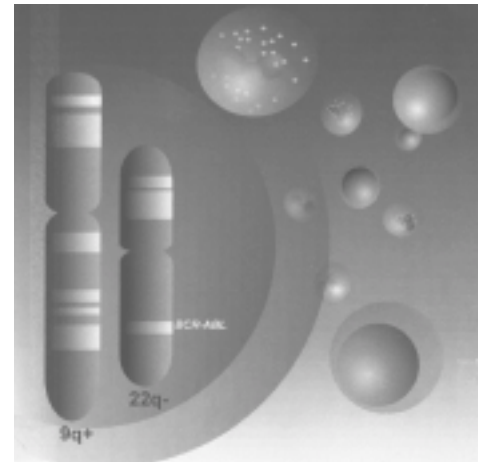
cer Institute in Buffalo, N.Y., before joining The Leukemia & Lymphoma Society. "It's very friendly to young, bright scientists as well as established investigators."

That's not to say that the 10 proposals funded with \$9.5 million—from combined 2002 and 2003 funds—lack scientific merit, Forsythe said. "As long as an investigator can elucidate the logic and the research that goes into developing a hypothesis and research question, if he or she can make a case for what they propose to study, we are willing to fund it," she said. "Sometimes people put things together in really interesting ways, so we're more likely to fund something that made us say, 'Oh my gosh, why didn't someone think of this before?'"

Once the panel finished rating the proposals, one last committee met to be certain that the proposals with the highest scores met the program goals set by the stakeholders. "We think it's money well invested and hope for good outcomes for medicines that can treat and cure CML," Kinniburgh said.

Today, Cranmer is in his second year of remission two years after receiving a bone marrow transplant from the youngest of his five brothers in March 2000 and going on Gleevec a year later. His hope for a cure hasn't waned, especially after reviewing the research proposals submitted to CDMRP.

"As a patient, you (usually) don't get to hear the backroom talks ... but after hearing these people who are so intelligent and so committed to finding a cure, you think, 'This is going to happen.'"



*CML is caused by a genetic defect that causes a change in chromosomes that makes a protein that's not normally made.*

## Lab's work on next-generation anthrax vaccine moves into clinical trials

The next-generation anthrax vaccine based on a decade of work at the U.S. Army Medical Research Institute of Infectious Diseases is now moving into not one, but four clinical trials.

The group at the institute did the legwork for the current vaccine candidates by singling out which protein

in *Bacillus anthracis*—the bacterium that causes anthrax—signals the body to produce immunity to the disease.

Early studies established definitively that the protein called “pro-

protective antigen” was just the component the vaccine would require, said Dr. Arthur Friedlander, a senior scientist at USAMRIID who directed the group's long-term effort.

After discovering the protein, researchers took the gene that codes for protective antigen and used recombinant DNA technology to try to produce the protective antigen in three expression systems: bacteria, yeast and viruses.

Ultimately, the team found bacteria was the best for producing the protein, and decided to grow the protective antigen in a non-disease causing strain of *B. anthracis*. The resulting recombinant protective antigen, or rPA, should provide a high degree

of safety in a vaccine because it's just one building block, a single protein of the organism that can produce an immune response.

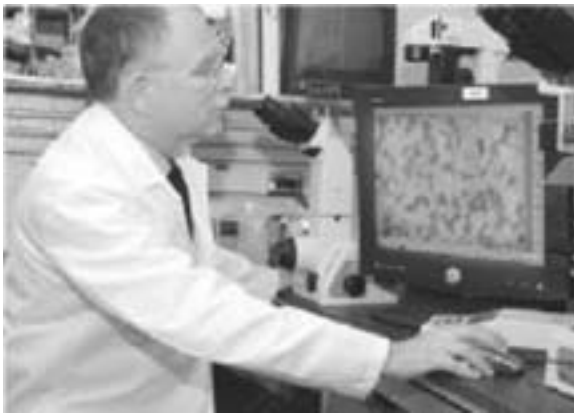
Researchers then proved it was effective in the best animal model available, the nonhuman primate. “What we did was identify it, purify it to a very high degree and showed that this protein by itself was protective in the most relevant animal model of human inhalational anthrax,” Friedlander said.

It is, according to numerous studies conducted at the institute.

In fact, not only is the rPA grown in *B. anthracis* effective, but USAMRIID's also shown that rPA grown in *E. coli*—an initiative put forward by Harvard researchers—is also effective in a rabbit model. Though tests on the *E. coli* rPA were not conducted on non human primates, Friedlander said the debate on which is best, rPA grown in *B. anthracis* or *E. coli*, is “likely a manufacturing issue not a substantive scientific issue.” He anticipates they will be equally protective.

“They are just different ways of expressing it,” he said. “When you clone the gene, because of the way that you splice it into one bacterium versus another, there may be very slight differences. The protein made in *B. anthracis* is the most native protein because it's the one the organism makes. The one made in *E. coli* may be slightly different because of the way it was cloned, but it's not likely that it would alter its ability to protect. You have to confirm that, and we have with this product.”

To date, two clinical trials that use the *B. anthracis*-based rPA are underway. VaxGen, based in Brisbane, Ca-



Dr. Arthur Friedlander, above, and his team at the U.S. Army Medical Research Institute of Infectious Diseases helped establish that the protein called “protective antigen” in *Bacillus anthracis* causes the body to produce an immune response.



**'Vaccine' from page 12**

lif., started its clinical trials at Baylor College of Medicine, Emory University School of Medicine, Johns Hopkins University and Saint Louis University Health Sciences Center under a contract from the National Institute of Allergy and Infectious Diseases. In a collegial effort, the National Institute of Allergy and Infectious Diseases, USAMRIID and the Joint Vaccine Acquisition Program have undertaken a Phase I clinical trial at the University of Maryland using a version of the original USAMRIID formulation manufactured at the National Cancer Institute-Frederick.

The University of Maryland trial will help advance the development of the other vaccines, said Dr. Lydia Falk, director of the Office of Regulatory Affairs, in the Division of Microbiology and Infectious Diseases at the National Institute of Allergy and Infectious Diseases.

"We can begin to compare the responses we see in humans to what had been observed in animals," she said. "That's a critical part of the development of these vaccines. The more preliminary investigative work that we can do, the more it benefits the entire field. Our hope is that the information we gain will be able to add to those building blocks that would lead to an accelerated development plan."

The formulation being used in that trial won't be pushed toward Food and Drug Administration licensing. "The product that is available and the one that was used during USAMRIID's pre-clinical studies had the rPA protein in one tube and an aluminum adjuvant in another tube, and before you injected it, you mixed the two," Falk said. "That's not an easy formulation to take to licensure." However this trial design will determine the value of including an adjuvant in the final vaccine formulation.

Two companies are currently using rPA grown in *E. coli* to create their next generation anthrax vaccine candidates. An rPA vaccine from the UK-based Avecia, under a contract with the National Institute of Allergy and Infectious Disease, will soon start Phase I clinical trials.

The second company, Dynport Vaccine Company, LLC, which licensed its rPA product from Avant, began its Phase I clinical trial April 28. The trial is being conducted by the Henry M. Jackson Foundation in Rockville, Md., which

routinely pursues vaccines for HIV for the military.

Because the foundation had an HIV vaccine candidate that used rPA as one of its two components "we decided to reprioritize our activities and commit to evaluating this protective antigen after the anthrax mail attacks in October 2001," said Dr. Merlin Robb of the Henry M. Jackson Foundation, the principal investigator for the foundation's clinical trial. "It (the rPA) was ready to go into humans to evaluate it for an anthrax indication. We sensed that it was a higher national priority."

Although the rPA vaccines are on an advanced development path toward Food and Drug Administration licensure, USAMRIID scientists still lend their expertise to vaccine manufacturers and the National Institute of Allergy and Infectious Diseases.

"Their contributions can't be overstated," said Dr. Ed Nuzum, the project officer providing technical oversight for the two National Institute of Allergy and Infectious Diseases contracts with Avecia and VaxGen. "Because of the work done at USAMRIID, as well as its counterpart in the United Kingdom, the Defence Science and Technology Laboratories, the rPA-based vaccine candidates are the most advanced second generation anthrax vaccines."

USAMRIID's early development work regarding animal studies and assay development will also be critical for developing animal models for Food and Drug Administration approval under the "Animal Rule." The rule, effective in July 2002, permits use of data from animal studies when efficacy studies of new drugs or biological products against chemical, biological, radiological or nuclear substances in humans is impossible because of the rarity of the disease or because human exposure to potentially lethal agents, like anthrax, is unethical.

"This is the first test case of the concept of licensing a vaccine based on animal efficacy data and trying to correlate that with the human immune response," Friedlander said.

Nuzum said he thinks the rPA vaccines are potentially the best vaccines to be going forward for licensure under the animal rule largely because of the work done at USAMRIID and DSTL. "The data, models and assays really are essential to the foundation for the work we're doing now," he said.

## People Making News

### Ursone lauds command's work at loggie conference



*Ursone*

"Far and away the best prize that life has to offer is the chance to work hard at work worth doing."

Those were the words President Theodore Roosevelt shared in 1903 and Brig. Gen. Richard Ursone borrowed while addressing attendees June 29 at a logistics conference hosted by the U.S. Army Medical Research and Materiel Command's Deputy Chief of Staff for Logistics.

"You have that prize every day: the chance of serving your great nation. I can't think of a more noble cause," said Ursone, who serves as the Assistant Surgeon General for Force Projection and Chief of the Medical Service Corps.

The three-day conference held at a Frederick hotel addressed supporting the warfighter through logistics excellence, which served as the event's theme. The conference hit on the issues facing logisticians today: facility sustainment, quality assurance, new defense logistics systems, maintaining medical equipment and more.

Giving the U.S. Army Medical Materiel Center, Europe, U.S. Army Medical Materiel Agency, the Health Facilities Planning Agency and the U.S. Army Medical Research Acquisition Activity as examples, Ursone posed the question: "Where would we be

without those four organizations that, day in and day out, are in the background but supporting soldiers who are on the tip of the spear?"

Reflecting on the importance of the command's work, the general spoke of memorial and funeral services he's attended for servicemembers who died in Afghanistan and Iraq.

"When you go to these memorial services and you look into the family's eyes ... you think of the tremendous sacrifice that those families have made, the commitment and then the sacrifice that the family will have to make long after we're out of Afghanistan and Iraq," he said. "It tells me that I have to work even harder to do my share to protect those young soldiers, to make sure that every ounce of my energy is focused on those great men and women."

The conference's keynote speaker, Ursone said he hoped those warfighters' sacrifices would continue motivating the people who work for the command.

"We all get tired. We all get bogged down. We all have bad days," he said. "But stop and think for a minute what you mean to that soldier on point and how your contributions can make a difference and may make a difference in saving the life of a soldier, sailor, airman or Marine."

### NCO Induction Ceremony

Twelve soldiers from the U.S. Army Medical Materiel Center, Europe and 418<sup>th</sup> Medical Logis-

## People Making News



*USAMMCE's newest NCOs*

tics Company, Fort Sam Houston, Texas, were inducted into the Noncommissioned Officer Corps of the U.S.

Army on Aug. 28 in a ceremony held at the Armstrong's Combined Club in Kaiserslautern, Germany.

Inductees Sgt. Robert Paradis, Sgt. Matthew Barlow and Sgt. Alunda Hopkins are currently assigned to the Information Management Division, USAMMCE. Inductees Sgt. Brandon Satterwhite, Sgt. Angela Nicolay, Sgt. Simon Ofosu, Sgt. Wa Pount, Sgt. Erika Street, Sgt. Leroy Priester, Sgt. James Welsh, Sgt. Marc Foti and Sgt. Debanish Velez are assigned to the 418th Medical Logistics Company and are currently deployed to USAMMCE in support of Operations Enduring Freedom and Iraqi Freedom.

During the ceremony, inductees vowed to uphold the Noncommissioned Officer Creed, crossed the "line of authority" of crossed sabers and signed the NCO Creed. Command Sgt. Maj. Craig A. Layton of the Landstuhl Regional Medical Center was the guest speaker for the event.

—Cheryl Navo, USAMMCE

### USARIEM welcomes new commander

Lt. Col. Karl Friedl became the 15th commander in the history of U.S. Army Research Institute of Environmental Medicine during

a ceremony in front of the Administration Building Aug. 22.

Friedl previously served as research area director for the Military Operational Medicine Research Program at the U.S. Army Medical Research and Materiel Command in Fort Detrick, Md., and replaces Col. John Obusek, commander of USARIEM since August 2000.

During the ceremony, Obusek also retired from the Army after 27 years of service. However, he almost didn't make it through his first day when a mix-up at guest housing prevented his newlywed wife, Christine, from staying with him.

"We came this close before turning around and heading back," Obusek said, holding up his hand, index finger and thumb spread 1 inch apart, as he looked at her during his remarks. An Army sponsor helped fix the problem. "The Army really is about great people. Over 27 years, I've witnessed this again and again, and I experienced that here at USARIEM."

He said it was a privilege to work on a mission that is vital to national security and has global impact as USARIEM products are being used around the world.

During the ceremony, Obusek received the Legion of Merit and certificates of appreciation from President George W. Bush, Gov. Mitt Romney, Sen. John F. Kerry and the surgeon general.

—By Curt Biberdorf, Natick Soldiers Systems Center

### Institute's support of women recognized

The U.S. Army Medical Research Institute of Chemical Defense was named the Organization Most Supportive of the Fed-

## People Making News

eral Women's Program's goals Aug. 14 at the Edgewood Area Conference Center at the Aberdeen Proving Ground Women's Equality Day Awards Ceremony, sponsored by the APG Federal Women's Program. The institute met the program's criteria of ensuring leaders comply with the spirit and intent of the FWP, including issuing a strong policy statement prohibiting sexual harassment and discrimination. The Maryland-based lab also supported the FWP's goals of providing women with high potential executive developmental assignments or high visibility projects to help them become optimally equipped for future opportunities as federal supervisors and managers, nominating women for long-term training, providing women with guidance for career development and having women in mid-level or senior positions.



*Signaigo*

### Women's Equality Day

Col. Jettaka Signaigo was the guest speaker at the 415<sup>th</sup> Base Support Battalion Women's Equality Day Celebration held at the Armstrong's Combined Club Aug. 26. Women's Equality Day commemorates the 1920 passage of the 19<sup>th</sup> Amendment to the Constitution, granting women the right to vote.

In her speech, Signaigo highlighted the struggle to pass the 19<sup>th</sup> Amendment and the great strides made in women's rights in the 83 years since its passage. Signaigo is the second female

commander of the U.S. Army Medical Materiel Center, Europe.

—*Cheryl Navo, USAMMCE*

### ICD investigator wins university award

Dr. Alfred M. Sciuto, a principal investigator at the U.S. Army Medical Research Institute of Chemical Defense, recently received the Towson University, College of Science and Mathematics, Dean's Recognition Award.

Each year, Towson's Alumni Association honors alumni who have distinguished themselves in their fields. Sciuto earned his bachelor of science in biology in 1972 and his master's degree in physiology in 1979 from Towson. He received his Ph.D. in physiology, toxicology and occupational medicine from The Johns Hopkins Medical Institutions in 1991.

Shortly after earning his doctorate, Sciuto joined the staff of USAMRICD as a research physiologist. The goal of his research is to develop models and evaluate therapeutic treatments against compounds or agents that are capable of causing acute lung injury.

Sciuto's research has resulted in 36 peer-review publications and five book chapters, as well as several technical reports and proceedings manuscripts. He is a peer reviewer for several scientific journals and guest editor for a special issue of *Inhalation Toxicology* on the respiratory effects of biological and chemical agents. He has been invited to submit chapters for two forthcoming book and a paper on phosgene for *Jane's Defense Weekly*.



## People Making News

In addition, as a recognized expert in his field, Sciuto is a regular technical consultant for the Phosgene Panel of the American Chemical Council.

Sciuto has also been an avid archeologist for the last 10 years. He is a member of the Archeological Society of Maryland and treasurer of the local Archeological Society of the Northern Chesapeake.

—Cindy Kronman,  
USAMRICD



U.S. Fish and Wildlife Service

### Appreciated donation

The U.S. Army Center for Environmental Health Research at Fort Detrick donated its pathology slides of fish and frogs to the Registry for Tumors in Lower Animals in Herndon, Va., in July. The donation was “in the best interest of the public

and the scientific community” as it will support a contract administered by the National Cancer Institute, according to Lt. Col. Rodger Martin, commander of USACEHR.

The slides will be added to the tumor registry and will aid in investigating neoplasms in medaka. “It is our hope that this material will be the foundation and an atlas of medaka histopathology and a source for study on background lesions in control medaka,” wrote Marilyn Wolfe, principal investigator in a letter thanking the center for the

donation. “The possibilities are exciting and we thank you for your generous contribution that will enable us to begin these projects.”

### Optometrist shares talents abroad

Getting a big kiss on her cheek for giving someone a pair of glasses isn’t an everyday occurrence for Army optometrist Lt. Col. Corina van de Pol. But then it’s not every day that she travels from Fort Rucker, Ala., to Mexico to perform hundreds of exams on people who otherwise might never see an eye doctor.

Van de Pol, along with three optometrists and six Lions Club volunteers carrying 2,500 pairs of used eyeglasses traveled to La Piedad, Mexico, June 12 through 15 to perform eye exams on more than 620 patients and dispense 500 pairs of glasses in two days.

“Nobody’s looked at their eyeballs before, and you can see they need glasses. You put them (glasses) on, and it’s instantaneous. They can see,” said van de Pol, who works as a researcher at the U.S. Army Aeromedical Research Laboratory. “It’s a life improvement that they would not have had otherwise.”

Lions in Sight of California and Nevada organized the journey as one of its 10 annual trips to Mexico that brings citizens free eye exams and free glasses collected from stateside Lions Club donation boxes.

The trip to La Piedad, outside Guadalajara, in June marked van de Pol’s 14th trip in 13 years. Of her trips to Mexico, Chile, Ukraine, Peru, Nepal, Zambia and Nigeria, most were with Lions in Sight, but others were with the military.



*Lt. Col. Corina van de Pol, a research optometrist with the U.S. Army Aeromedical Research Laboratory, examines a patient's eyes during a trip to Mexico that was sponsored by Lions in Sight, a non-profit organization that brings free eye exams and eyeglasses to people who don't have access to them.*

"You can make such a great impact on somebody's life with something that we (doctors) would consider minimal effort," she said.

#### Awards at Headquarters

On July 29 the following individuals from the U.S. Army Medical Research and Materiel Command received awards:

❖ Col. Erik Henschel, U.S. Army Medical Research Institute of Infectious Diseases, received the Legion of Merit for his work as chief of the Diagnostics Systems Division.

❖ Lt. Col. George Korch, USAMRIID, received the Legion of Merit for serving as chief of the Virology Division, deputy commander of USAMRIID and as an epidemiology and entomology consultant in Kuwait.

❖ Maj. Robert von Tersch, USAMRMC, received the Defense Meritorious Service Medal

for his work as the scientific adviser for the Assistant Secretary of State with for Nonproliferation Nonproliferation Bureau.

❖ Maj. Chessley Atchison, U.S. Army Medical Research Institute of Chemical Defense, received the Meritorious Service Medal for serving as the executive officer, chief of the Administration Division and research coordinator for the institute.

❖ Master Sgt. Nicole Klages, USAMRMC, received the Meritorious Service Medal for serving as operations noncommissioned officer for the 100<sup>th</sup> Medical Detachment, 30<sup>th</sup> Medical Brigade.

❖ Lt. Col. Harold Modrow, U.S. Army Medical Materiel Development Activity, received the Army Commendation Medal for his work with an investigational new drug, the hemostatic dressing, during Operations Enduring Freedom and Iraqi Freedom.

❖ Col. Lisa Weatherington received the Military Outstanding Volunteer Service Medal for her work with elementary and middle school children in a Maryland county and her church and speaking engagements in the region.

❖ Patrick MacKenzie was recognized for his nomination for the Secretary of the Army's Award for Outstanding Achievement in Equal Employment Opportunity.

❖ Patricia Fritz and Jennifer Merriman, USAMRMC, were recognized for their 30 years of federal service.

❖ Roxanne Cannon, USAMRMC, was recognized for her 25 years of federal service.

#### Order of Military Medical Merit

Dr. Richard Kenyon, program manager for the Breast Cancer Research Program of the Congressionally Directed Medical

## People Making News



*Kenyon*

Research Program, received the Order of Military Medical Merit Aug. 21 from Col. Kenneth Bertram, CDMRP director. Kenyon was recognized for a career of biomedical science and service to the command at Fort Detrick.

### Tech transfer award



*Golenda*

Claudia Golenda of the Walter Reed Army Institute of Research received the 2003 Regional Coordinator's Excellence Award for the Federal Laboratory Consortium Mid-Atlantic Region Sept. 11. The award, presented annually for technology transfer, recognizes individuals who make a significant contribution to the FLC program during the year.

Golenda was recognized for the work she did with nonprofit organizations to bring funds into the federal government.

"Last year at WRAIR we did three CRADAs (cooperative research and development agreements), bringing in several million dollars," Golenda said.

Being selected as a recipient for the competitive award is a tremendous honor that recognizes the excellence of her technology transfer efforts. Her winning nomination will be submitted for the 2004 National FLC Representative of the Year Award.

### Disney visit

As part of a trip to the Natick Soldier System Center, representatives from Walt Disney Entertainment and Costuming spent an afternoon with the U.S. Army Research Institute of Environmental Medicine Sept. 3.

The Disney costuming team has to deal with many of the same issues the military has with its forces. They are concerned about the biophysics of clothing, hydration, heat stress, work-rest cycles, and more. Many of Disney's parks are in warmer climates, and they are understandably concerned about the safety of their employees.

Lt. Col. Beau Freund, Bruce Cadarette and Larry Berglund gave presentations about work at USARIEM that addresses the Disney team's concerns and is another example of how military research and development applies to the civilian sector.

—*Christopher Joyce,*  
*USARIEM*

### Chief of Staff visit

Gen. Peter Schoomaker, the 35<sup>th</sup> Army chief of staff, visited a Deployable Medical Systems warehouse while

touring Sagami Depot, Japan, Sept. 8. U.S. Army Medical Materiel Agency contractor Chuck Davis was preparing for the upgrade of four hospitals that are prepositioned at that location and had a few moments to explain USAMMA's mission there to Schoomaker.



*Davis and Schoomaker*